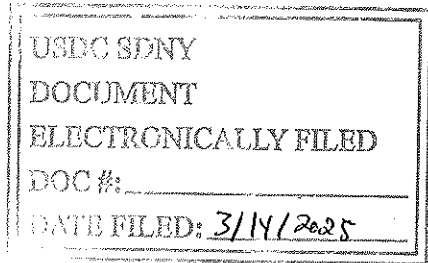


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



UNITED STATES OF AMERICA, et al. *ex rel.* Uri Bassan,

Plaintiffs,

-against-

15 Civ. 4179 (CM)

OMNICARE, Inc.,
Defendant

UNITED STATES OF AMERICA,
Plaintiff

OMNICARE, INC. and CVS HEALTH CORP.,
Defendants.

RESERVED EVIDENTIARY RULINGS

McMahon, J.:

For rulings relating to the outstanding “subsequent remedial measures” objections:

The Government represented to me that it would provide me with a copy of the Standard Operating Procedure #40 (“SOP 40”) that was in effect since 2008, which, per the Government’s representation, required Omnicare not to use “rollover” dispensing to fill prescriptions at facility types where such “rollovers” are not allowed. The Government’s representation appears to have been intended to convince me that no “subsequent remedial measure” was put in place in 2016, such that all objections on the ground that there were changes to Omnicare’s policies regarding dispensations in long-term care facilities should be overruled.

The document that I was instead provided with was OCRSDNY00060639—a document that, on its face, proves nothing of the kind. This document is not the SOP 40 that was in place at Omnicare in 2008. It is, rather, the fifth iteration of an SOP 40 (Section Four: Corporate Compliance Requirements) that apparently was originally issued (in a form not made available to me) on February 1, 2008, and that was repeatedly REVISED (which in my dictionary means “CHANGED”) on four subsequent dates: February 1, 2009; August 1, 2009; January 1, 2013; and

February 16, 2016. The document I have been given appears to be the fourth revision, issued on February 16, 2016.

I harbor no doubt that Omnicare has had a SOP 40 in place since 2008. I am equally sure that the 2016 version of the policy is NOT the same policy that was issued on February 1, 2008, but is a rather substantially revised policy. After reading the deposition testimony of the late Jo Sharpe, I understand that the 2016 revision was put into place to deal with compliance issues that arose in 2014.

I do have the 2013 version of the policy. *See* GX-415-2. The first page indicates that it is a revision of the original policy, OCRSDNY00078326, which means that it is not the same as the original 2008 policy. It is also manifestly not the same as the February 2016 “revision.” The 2013 revision requires that “each prescription dispensed as part of a Cycle Fill must have a corresponding authorization to refill from the facility or customer” and that it “must be maintained by the pharmacy along with other refill request documents.” OCRSDNY00078327. It states that all Cycle Fill prescriptions, both new and refill, are to be verified by a pharmacist. *Id.* It says nothing about any computer coding. It is not until 2016 that the policy was “revised” (changed) to include explicit requirements for dispensing at Cycle Fill facilities. It is not until the 2016 revision that the policy required that “dispensing systems” be “set up to identify facility types where ‘rollover’ prescriptions are not allowed.” OCRSDNY00060639. It is not until 2016 that the revised policy states that “the pharmacies will obtain new prescriptions prior to dispensing medications,” and “Medications without valid, current prescriptions cannot be dispensed.” *Id.* (emphasis in the original). And it is not until 2016 that the policy provides “Extra preparation will be necessary for Assisted Living Facilities [non-skilled nursing facilities] as their prescriptions do not ‘rollover.’” *Id.* Moreover, the 2016 revision includes specific coding instructions that are not in the 2013 revision. All of this new policy information can be found on the first page of the 2016 revision document. *Id.* The only portion of the 2016 revision that conforms (roughly) to what is in the 2013 revision is found on page 2 of the 2016 policy, under the heading “Authorization to Fill Prescriptions.” *See* OCRSDNY00060640; OCRSDNY00078327.

It may well be that it was the intention of Omnicare simply to make more explicit a requirement that had always been in existence—I gather the Government has testimony from at least one Omnicare witness to that effect. However, Omnicare takes the position that it “revised” the policy substantially in 2016—specifically by changing the coding so that prescriptions at “retirement” facilities could not roll over—and that this qualifies as a subsequent remedial measure after learning that many of its long-term care pharmacies were not doing what the earlier policy required—which had led to some adverse findings from various state pharmacy boards. I cannot think of a better description of the 2016 “revision” than a “subsequent remedial measure.” And as will be seen when I discuss individual documents below, a different Omnicare employee opined that the February 2016 revision to the policy represented one of the “biggest changes” to Omnicare’s operations.

Even if the Government is correct that it was always Omnicare’s “policy” to follow the law, its principal assertion in this case is that the “policy” was honored IN THE BREACH! Explicit instructions to deal with rampant violations of policy—instructions that are not at all apparent from

earlier iterations of the policy—qualify as subsequent remedial measures. The thing they are remediating is the repeated breach.

The Government thus cannot introduce evidence about the implementation of changes to existing policy—revisions that appear to me to be additions to, not simply explanations of, the 2013 version of the policy—in order to establish liability without running afoul of Fed. R. Evid. 407.

The question, then, is whether any of the documents as to which a decision on admissibility was reserved at the Final Pretrial Conference, (1) can be admitted to prove liability because it does not contain evidence of any subsequent remedial measure, but rather is limited to discussion about the need to revise the policy (which is not barred by Fed. R. Evid. 407); or (2) cannot be admitted to prove liability but can be admitted for some more limited purpose pursuant to another rule of evidence. To the extent that my below rulings sustain Fed. R. Evid. 407 objections, they do so on the assumption that the evidence is being offered to prove culpable conduct by Omnicare. “Nevertheless, evidence of such measures may be introduced for other purposes, such as impeachment or—if disputed—to prove ownership, control, or the feasibility of precautionary measures.” *Lidle v. Cirrus Design Corp.*, 505 Fed. Appx. 72, 75 (2d Cir. 2012).

Herewith my rulings:

GX-5-1, GX-5-3, GX-5-4: The parties have agreed on redactions to GX-5-1 (CVSBASSAN00001919-20) that the Court finds to be appropriate. GX-5-3 and GX-5-4¹ appear to be a further (and more concise) statement of the February 2016 revision. As such, they are not admissible to prove liability, because they—and more precisely, the statements at Section II.A.3 of that document—are simply a summary of the remedial measures that Omnicare chose to take in February 2016. Allowing this document into evidence is no different than allowing the February 2016 revision into evidence. This is evidence of the implementation of the revision to the policy. **Objection sustained as to GX-5-3 and GX-5-4. Not admitted. GX-5-1 is admitted with the agreed-upon redactions.**

GX-40: This is an email chain, dated March 2016, in which an Omnicare employee posits that the 2016 revision to SOP 40 qualifies as one of the “biggest changes” to Omnicare’s operations and links the reader to <http://new.my.omnicare/sites/compliancepolicies/SOP40> (please note the use of the word “new” in the link). The email also announces SOP 40 revision #4 and directs Omnicare dispensers to comply with it. The circulation of the SOP qualifies as the “implementation of the new policy,” so this email chain, which is primarily an announcement of the new version of SOP 40 to those tasked with following it, is no more admissible than is the actual text of the revised policy itself. I do note that, in the second email in this short chain, the speaker indicates that the February revision I discussed above was “pulled back right after release.” I do not have a March version, although the April revision (GX-5-3/GX-5-4) indicates that there was a March revision, and the date when this email was circulated is March 3, 2016—consistent with a March 1 revision. **In any event, objection sustained. Not admitted.**

¹ GX-5-4 appears to be a duplicate of GX-5-3.

GX-62: This email chain, dated February 2016, refers to the new policy that was coming and asks an employee to “take a pass at revising the SOP” to include “more specifics....so they can’t have roll over.” This is a reference to the need for a policy; it is not the subsequent remedial measure, but rather a discussion about the need for such a measure and about what measures ought to be integrated into a new policy. This is not barred by Fed. R. Evid. 407. **As such, objection overruled as to GX-62. Admitted. However, GX-62-1 and GX-62-2 appear to be first passes at—and essentially—the revised policy that was finalized two weeks later. To them, objection sustained. Not admitted.**

GX-63: This email was written by the person who was tasked with “taking a pass at revising the SOP.” The author is “physically sick to [her] stomach” and “want[s] to die” but thinks she has written a document that “captures how to run a compliant Cycle Fill.” GX-63 qualifies as a “discussion about revising the policy,” which is NOT the subsequent remedial measure and so is **admitted**. I note that the Second Circuit has not yet spoken to the precise issue of whether discussions leading up to the implementation of a subsequent remedial measure are inadmissible under Fed. R. Evid. 407, and district courts go both ways. *See e.g., Rollins v. Board of Governors for Higher Edu.*, 761 F. Supp. 939, 942 (D.R.I. 1991) (contemplated action not admissible); *Hochen v. Bobst Group, Inc.*, 193 F.R.D. 22, 25 (D. Mass. 2000) (contemplated action admissible). But the only Circuits we have found that have spoken to that issue have concluded that such discussions are not inadmissible under Fed. R. Evid. 407, and I find their reasoning persuasive. *See e.g., Brazos River Authority v. GE Ionics, Inc.*, 469 F.3d 416, 430 (5th Cir. 2006); *Benitez-Allende v. Alcan Aluminio do Brasil, S.A.*, 857 F.2d 26, 33 (1st Cir. 1988).

That said, GX-63-1, GX-63-2 and GX-63-4, GX-63-5 are essentially the revised policy, and to them, **objection sustained, not admitted**. GX-63-3 is an excerpt from the pre-existing “user guide.” Though I do not see how it will be relevant, it is not barred by Fed. R. Evid. 704. I also note that no objection on relevance grounds was interposed as to GX-63-3. **It is admitted.**

GX-96: This email chain, dated February 2018, indicates that 710 Omnicare pharmacies will need to “update unit flags that control prescription renewal functionality in Oasis.” The email goes on to propose “actions” that the facilities must undertake in order to “update facility flags for prescription renewal” in the Oasis program. GX-96-1 provide the instructions to be sent to the facilities. This qualifies as a subsequent remedial measure for Oasis, which I understand was implemented in 2018. As such, **objection sustained. Not admitted.**

GX-120: This email chain, dated June 2018, deals with compliance with the updated SOP 40 policy at non-skilled nursing facilities (“non-SNFs”). Omnicare compliance officers “validat[e] that [OmniDX] retirement flags for non-SNF facilities have been flipped to yes.” As I understand, Omnicare modified OmniDX’s Cycle Fill coding to prevent rollover dispensing via the Cycle Fill program in the February-March 2016 period (it sent out a change to SOP 40, then pulled it back and revised it, then sent it out again in March 2016). That is the change that qualifies as a subsequent remedial measure. I further understand that Omnicare then reversed field and, sometime in 2017, changed the coding back to the way that the Government contends leads Omnicare to violate the False Claims Act. Dkt. No. 636-15 at 3. And then, as I understand it, the coding was permanently changed to disallow rollovers sometime in 2018. Is this the *second* subsequent remedial measure dated 2018—one that has since remained in place? **The parties need**

to provide me with some context before I can make a ruling. And please correct my understanding of the relevant dates if it is wrong.

GX-146: This email exchange, dated June 2018, informs Omnicare pharmacists about a universal change to OmniDx to prevent improper rollover. **For the same reasons as those stated above, the parties need to provide me with some additional context.**

GX-147: This email exchange is dated June 2017—more than a year after the subsequent remedial measure for OmniDX was put into place and at or about the time that Omnicare reversed field and undid the remedial measure. It appears to be an email chain discussing internal audit issues at Omnicare, which may or may not include auditing of the changes made a year earlier—I don't see any obvious references to those changes. But this particular email chain is not evidence of any subsequent remedial measure. I question its relevance, however, and am inclined to sustain the Fed. R. Evid. 401 relevance objection raised by Omnicare. The parties have not argued this objection. **We will discuss this the next time we are together.**

GX 156: This email from William Glaser to Dan Sinclair, dated May 16, 2017, seems to contain an attachment (see bottom of first page), which is undated, so we do not know when the content that appears at the top of the second page of this exhibit (down to the word "Dan") was created. Much of it is admissible—actually, the only part of this "attachment" that would even arguably be inadmissible is the first paragraph under "Background," which appears to reflect the subsequent remedial measure that was taken in 2016. But without knowing (1) whether I am correct that this is in fact a portion of a document that was created earlier; and (2) when and in what context the "attachment" was created, I cannot figure out whether that one paragraph is barred under Fed. R. Evid. 407. It is my understanding that, by the date of the Glaser-to-Sinclair email (May 16, 2017), the remedial measure had already been rolled back. **I need additional information in order to rule.**

GX-157: This email chain from 2018 consists of a discussion about possible changes to some policy dealing with rollovers. It is not a policy; it is purely background to the possible adoption of a policy. It is not barred by Fed. R. Evid. 407. **Objection overruled. Admitted.**

GX-158: The earliest email in this September 2018 email chain explains (or appears to me to explain) why the 2016 changes to OmniDX were implemented and why no changes were made to Oasis at that time. The subsequent emails are comments from people who received the original email (from Dan Sinclair). They are not evidence of any subsequent remedial measure involving Oasis that was implemented in 2018; they may be admissible as evidence of discussions about whether there was a need to fix something in Oasis that was overlooked in the past. As such, **objection overruled. Admitted.**

GX-173, GX-173-3, GX-173-6: This email also discusses the fact that the 2016 "project" was limited to OmniDX and made no changes to Oasis. It is pure background. This is not a subsequent remedial measure. GX-173-3 contains instructions for a survey document, which tasks people with providing certain information. GX-173-6 appears to be that survey document (not yet filled out). Nothing in these attachments qualifies as a subsequent remedial measure. There is no discussion of the subsequent remedial measure of recoding. **Objection overruled. Admitted.**

GX-176: This is another collection of separate documents, dated February 2017, that should have been separate exhibits. There is nothing remotely inadmissible about the cover memo (GX-176). GX-176-1 and GX-176-2 are documents detailing how to turn off the rollover function in OmniDX and Oasis. GX-176-3 lists action items with deadlines. These action items begin with identifying those facilities currently set up to allow rollover and removing rollover capabilities on both Oasis and OmniDX for facilities not eligible for rollover. **The parties need to educate me further. I frankly do not understand the relevance of either of these documents or how they qualify as evidence of subsequent remedial measures.**

GX-194: This seems to be the document that began the process of doing some sort of overhaul to Oasis in 2018—probably leading to the implementation of what has been called the Oasis subsequent remedial measure. It is purely background and is not itself the subsequent remedial measure. Indeed, at the time these emails were sent, it does not appear that any new policy had been adopted. **Objection overruled. Admitted.**

GX-209: This is an email attaching a compliance risk assessment dated April 27, 2016. It is not a subsequent remedial measure. **Objection overruled, admitted.** If there are compliance issues that should be redated the parties need to take care of that.

GX-213: CVSBASSAN00001751-1759 are duplicated in GX-5-1, GX-5-3/GX-5-4. The same ruling and redactions stated above apply here. With regard to CVSBASSN0000150 (the first page of the exhibit), there is only a reference to a “rollover issue.” This does not qualify as a remedial measure and so **this page is admitted.**

GX-303: GX-303 is an email chain, dated April 2016, circulating an updated SOP 40, to regional “LTC Pharmacy Site Leaders” with SOP 40 (April 4, 2016) as an attachment (GX-303-1). Incidentally, GX-303-1 is GX-5, and the same ruling applies. GX-303 is implementation of a subsequent remedial measure. Indeed, the Omnicare Operations Compliance team expressly directs recipients to the “biggest changes,” including Section II.A.3. OCRSDNY00051258. **Objection sustained, not admitted.**

GX-415 and GX-415-3: The cover email chain, dated March 2016, indicates that the fourth revision to SOP 40 (GX-415-3) was circulated through Omnicare in 2016. This qualifies as implementation of a subsequent remedial measure. **Objection sustained, not admitted.**

GX-416: The only page of this exhibit that even arguably runs afoul of Fed. R. Evid. 407 is one slide of a deck titled “operations compliance update” dated March 28, 2017 (GX-416-1). The slide in question specifically states that the subsequent remedial measure that had been implemented in 2016 (*see* GX-418 below) had been rolled back. OCRBASSAN01242446. That is not a subsequent remedial measure—this is the *rollback* of a subsequent remedial measure. And knowing that the coding was previously changed is necessary to give the rollback context. **Objection overruled. Admitted. The jurors will be told that they may not consider the original coding change as evidence that Omnicare was previously doing anything wrong.**

GX-418: These emails reference an attached slide deck that discusses an “operations compliance update” dated February 22, 2017 (GX-418-1). One slide in the deck instructs “each pharmacy to review and validate [that] all active facilities are entered into the dispensing system correctly,” with reference to the program changes in Oasis and OmniDX. OCRBASSAN01526005. This is the subsequent remedial measure referenced above at GX-416-1. The rest of the document is of no probative value. For that reason, **objection sustained. Not admitted.**

GX-500: This appears to be an email chain, dated February 2017, attaching an “Oasis Updating Patient Default Pharmacy Guide” (GX-500-2) as well as a “list of facilities that will require updates to the default customer class at both the facility and customer level” (GX-500-1). See OCRSDNY00045740. The email expressly provides that there is “action needed” to bring the identified pharmacies into conformity with the new policy. This appears to be a subsequent remedial measure. **Objection sustained. Not admitted.**

Dated: March 14, 2025

A handwritten signature in black ink, appearing to read "C. J. H.", is written over a horizontal line.

U.S.D.J.

BY ECF TO ALL COUNSEL